DAIDS
Bethesda, MD USA

PROCEDURE

Procedure for the Destruction of Clinical Trial Specimens owned by NIAID

Approval Date: 25 AUG 2009 No.: DWD-SOP-LB-004.01
Effective Date: PENDING DRAFT

1.0 PURPOSE

This procedure describes steps for the destruction of laboratory specimens from all National Institute of Allergy and Infectious Disease (NIAID) Division of AIDS (DAIDS) -supported and/or -sponsored clinical research in the custody of DAIDS supported laboratories or repositories.

2.0 SCOPE

This procedure applies to specimens obtained from NIAID (DAIDS) -supported and/or -sponsored clinical research that are: 1) the property of NIAID and 2) stored at DAIDS supported and/or sponsored laboratories or repositories. This procedure is applicable to the following laboratories and repositories: AIDS Vaccine Evaluation Group (AVEG) laboratories, HIV Network for Prevention Trials (HIVNET) Laboratories, and the DAIDS repository contractor SeraCare BioServices, Gaithersburg, MD. Unless otherwise stated, specimens collected by contractors are the property of the NIAID; specimens collected by grantees (including cooperative agreements) are the property of the awardee institution[1]. This procedure does not apply to specimens that are property of awardee institutions from research supported through grants and cooperative agreements.

Note: For studies that are co-funded by DAIDS and other parties, a written agreement is needed regarding the application of the procedure and/or process to be followed for stored specimens.

3.0 BACKGROUND

The DAIDS -supported and/or -sponsored laboratories and repositories receive and store samples from NIAID (DAIDS) -supported and/or -sponsored clinical trials conducted both domestically and internationally. If a clinical research participant does not provide consent for the samples to be retained, all laboratory specimens provided by the participant should be destroyed as indicated by the IRB/EC or as dictated by institutional policies. In cases where NIAID owns the research samples, a DAIDS Project Officer (PO) determines which specimens the laboratory or repository can either destroy or maintain in storage.

This procedure describes steps DAIDS considers adequate for determining which NIAID owned laboratory samples are eligible for destruction.

[1] http://www3.niaid.nih.gov/LabsAndResources/resources/reposit/guidance.htm

4.0 DEFINITIONS

For definitions, see DAIDS glossary:

http://www3.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Glossary.htm

5.0 RESPONSIBILITIES

DAIDS

DAIDS is responsible for making decisions about the storage, future use and destruction for DAIDS clinical trial specimens owned by NIAID, consistent with the protocol, informed consent and relevant regulations, and for notifying the investigator/ laboratory of its decisions.

Laboratory staff

Laboratory staff is responsible for ensuring that the specimens from NIAID (DAIDS) -supported and/or -sponsored clinical trials are stored according to protocol requirements in a Good Clinical Laboratory Practice (GCLP) compliant manner. Once DAIDS notifies the laboratory to destroy specimens, laboratory staff is responsible for implementing this DAIDS procedure and following instructions for specimen destruction.

Principal Investigator

The *Principal Investigator* is responsible for ensuring lab specimens from NIAID (DAIDS) -supported and/or -sponsored clinical trials are stored and ultimately destroyed in accordance with this procedure, institutional polices, and any applicable local or country laws in a GCLP compliant manner.

6.0 POLICY

6.1 Notification

6.1.1 The Principal Investigator/ laboratory staff will be notified by DAIDS PO if specimens from NIAID (DAIDS) -supported and/or -sponsored clinical trials owned by NIAID need to be destroyed. Because research may be conducted in a variety of U.S. domestic and international settings, and across diverse populations, investigators are advised to contact their local IRB/EC or legal counsel at their institution for guidance about any additional requirements, local

regulations, laws and institutional policies related to specimen destruction.

6.1.2 DAIDS will provide the laboratory with a list of protocols/specimens and a date by which the specimens need to be destroyed. This notification may also include any special requirements for destruction and documentation.

6.2 Verification

6.2.1 Laboratory staff will check specimen inventories to ensure the specimens are stored in the facility. Laboratory staff will note and resolve any discrepancies such as specimen type, numbers, source protocol, etc., before destruction.

6.3 Documentation

6.3.1 Laboratory staff should provide the following information using the format outlined on the "List of Samples from DAIDS -supported and/or -sponsored clinical trials destined for destruction" Table (see Appendix 1): protocol number, notifying authority, type and number of specimens destroyed, date & time of destruction, Laboratory staff member's signature & date and the Laboratory Director or designee's signature & date.

6.3.2 In accordance with DAIDS GCLP Standards, a list of samples from DAIDS –supported and/or -sponsored clinical trials destined for destruction (see Appendix 1 List of Samples from DAIDS -supported and/or -sponsored clinical trials destined for destruction) should be maintained at the site[2].

6.3.3 If the laboratory uses LDMS, specimens will be removed from the specimen storage section of the LDMS.

6.3.3.1 Comments should be made in the specimen management section about the destruction of the samples along with the sample destruction date.

6.3.3.2 Copies of the storage reports will be kept by the laboratory.

[2] http://www3.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/PDF/GCLP.htm

6.4 Discarding of samples

6.4.1 All applicable institutional policies, and local or national regulations are to be followed when handling or discarding specimens.

6.5 Confirmation

6.5.1 Confirmation of destruction will be sent out to DAIDS according to DAIDS instructions.

7.0 REFERENCES

HPTN/MTN Laboratory manual (Version 1.0, 15 November 2006): Sample Destruction
http://www.hptn.org/web%20documents/CentralLab/HPTN-MTNLABMANUALVersion1.0.pdf

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

10.0 CHANGE SUMMARY

This procedure is the first version. It does not supersede any other version.

11.0 APPENDICIES

Appendix 1 - List of Samples from DAIDS -supported and/or -sponsored clinical trials destined for destruction [LB.404]